

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 09/869,333
Filing Date: 07/26/2001
Applicant: Franco Pamparana
Group Art Unit: 1614
Examiner: Raymond J. Henley III
Title: ESSENTIAL FATTY ACIDS IN THE PREVENTION OF
CARDIOVASCULAR EVENTS
Attorney Docket: 6794-000141/US/01

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION

The patents, publications and other information requested to be considered by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

II. COPIES

A. ☒ Submitted herewith is a legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office; (iii) each unpublished U.S. application listed below in Section IV (i.e., including the specification, claims, and any drawing of the application, or that portion of the application which caused it to be listed, including any claims directed to that portion), except for such applications filed on or after June 30, 2003, pursuant to the Waiver of the Copy Requirement in 37 C.F.R. 1.98 (OG Notice dated October 19, 2004); and (iv) all other information or that portion which caused it to be listed.

B. ☐ Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number

U.S. Filing Date

C. ☐ This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search report are listed on the attached Form 1449 for consideration by the Examiner and for listing on any patent resulting from this application. If the International Search report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g).)

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. ☒ Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. ☐ A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. ☐ See the attached foreign patent office communication from a counterpart foreign application:

2. ☐ English translations are provided:

3. ☐ Other:

C. ☐ The following additional information is provided for the Examiner's consideration.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. ☐ The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does (do) not waive the confidentiality provisions of 35 U.S.C. § 122.

Serial No.

Filing Date

Inventor(s)

V. THIS IDS IS BEING FILED UNDER

A. ☒ **37 C.F.R. § 1.97(b):** (check only one box)

1. ☐ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.

2. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or certification is required.

3. ☐ before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

4. ☒ before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. ☐ **37 C.F.R. § 1.97(c):** (check only one box)

before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.

1. ☐ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

2. ☐ See the certification below. No fee is required.

C. ☐ 37 C.F.R. § 1.97(d):

after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.

1. ☐ See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e): (check only one box)

The undersigned hereby certifies that:

A. ☐ each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F.R. 1.704(d) below in section VII, if applicable; or

B. ☒ no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).

C. ☐ some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 C.F.R. 1.704(d)

The undersigned hereby states that:

☐ each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box, if applicable)

A. ☐ A check in the amount of \$180.00 is enclosed for the above-identified fee.

B. ☐ Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-identified fee. A duplicate copy of this paper is attached.

Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.


The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

Respectfully submitted,

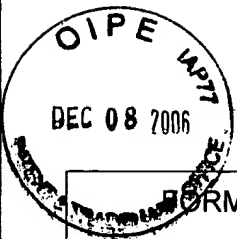
Dated: December 8, 2006

By: _____


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| FORM HDP-1449 (Based on Form PTO-1449) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Sheet 1 of 1 | ATTORNEY DOCKET No. | SERIAL No. |
| | 6794-000141/US/01 | 09/869,333 |
| | APPLICANT | |
| | Franco Pamparana | |
| | FILING DATE | GROUP |
| | July 26, 2001 | 1614 |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|---------------------|-----------------|------|------|-----------------|------------------------------|
| Ref. Desig. | Examiner's Initials | Document Number | Date | Name | Class/ Subclass | (If appropriate) Filing Date |
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| FOREIGN PATENT DOCUMENTS | | | | | | | |
|--------------------------|---------------------|-----------------|------|---------|-----------------|-----------------------|--|
| Ref. Desig. | Examiner's Initials | Document Number | Date | Country | Class/ Subclass | Translation Yes No | |
| | | | | | | | |

| OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.) | | |
|--|---------------------|---|
| Ref. Desig. | Examiner's Initials | |
| 1. | | GISSI-Prevenzione Investigators , <i>Dietary supplementation with n-3 polyunsaturated fatty acids and vitamin E after myocardial infarction: results of the GISSI-Prevenzione trial</i> , The Lancet (1999) Vol. 354, 447-455 |
| 2. | | Christine M. Albert, M.D., et al. , <i>Blood Levels of Long-Chain n-3 Fatty Acids and the Risk of Sudden Death</i> , N. Engl J. Med, (2002) Vol. 346, No. 15, 1113-1118 |
| 3. | | Maggie B. Covington, M.D. , <i>Omega-3 Fatty Acids</i> , American Family Physician (2004), Vol. 74, No. 1, 133-140 |
| 4. | | Chenchen Wang MD et al. , <i>Effects of Omega-3 Fatty Acids on Cardiovascular Disease</i> , AHRQ Publication No. 04-E009-2 (2004) Evidence Report/Technology Assessment No. 94 |
| 5. | | TRICOR® 48 mg and 145 mg , (fenofibrate tablets), Abbott Laboratories (2004) pp. 1-8 |
| 6. | | The Field Study Investigators , <i>Effects of long-term fenofibrate therapy on cardiovascular events in 9795 people with type 2 diabetes mellitus (the FIELD study): randomized controlled trial</i> , www.thelancet.com (2005), pp. 1-13 |
| 7. | | The Allhat Officers and Coordinators of the Allhat Collaborative Research Group , <i>Major Cardiovascular Events in Hypertensive Patients Randomized to Doxazosin vs. Chlorthalidone</i> , JAMA (2000) Vol. 283, No. 15, 1967-75 |
| 8. | | CARDURA® (doxazosin mesylate) Tablets , Pfizer Inc. (2002) pp. 1-19 |
| 9. | | Thalitone® , Monarch Pharmaceuticals® (2004) |

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| Examiner: | Date Considered: |
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EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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